510(k) Summary

K060118

Specialty Spine Products
SSP Pedicle Screw System

JUN - 8 2006

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Specialty Spine Products, LLC 4121 Tigris Way Riverside, CA 92503 Telephone (951) 687-2808 Fax (951) 734-7594
Official Contact:	Angela Carlson
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation
Trade/Proprietary Name:	SSP Pedicle Screw System
Common Name:	Pedicle screw spinal system

ESTABLISHMENT REGISTRATION NUMBER

Specialty Spine Products will submit Establishment Registration to FDA prior to marketing the SSP Pedicle Screw System.

DEVICE CLASSIFICATION

Pedicle screw spinal systems are classified as Class II devices (21 CFR 888.3070). The product code for Orthosis, Spondylolisthesis Spinal Fixation is MNH. The product code for

Orthosis, Spinal Pedicle Fixation is MNI. These device classifications are reviewed by the Orthopedic Devices Branch.

INTENDED USE

The SSP Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

The SSP Pedicle Screw System also is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, spinal stenosis, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

DEVICE DESCRIPTION

The SSP Pedicle Screw System is an internal fixation device for spinal surgery consisting of rods, pedicle screws and transverse links. To enable close conformance to patient anatomy, pedicle screws and rods are available in various lengths, diameters, and/or contours. A series of manual surgical instruments (not a subject of this submission) intended to assist the insertion and placement of the implants are provided in an instrument tray.

EQUIVALENCE TO MARKETED PRODUCT

Specialty Spine Products, LLC has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the SSP Pedicle Screw System is substantially equivalent in indications and design principles to predicate devices that have been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2006

Specialty Spine Products, LLC
c/o Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K060118
Trade/Device Name: SSP Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: May 16, 2006
Received: May 19, 2006

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

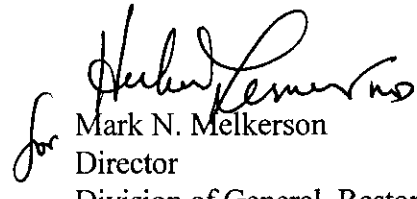
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060118

Device Name: SSP Pedicle Screw System

Indications for Use:

The SSP Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients undergoing fusion by autogenous bone grafting having implants attached to the lumbar and sacral spine with removal of implants after the attainment of a solid fusion.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K060118

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